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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,764	07/10/2001	Clifton A. Alferness	1759-12	8600

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/29/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/901,764

Applicant(s)

ALFERNESS ET AL.

Examiner

Jonathan ML Foreman

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-- Th MAILING DATE of this communication appears on the cover sheet with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-18 and 28-32 is/are allowed.
- 6) ☒ Claim(s) 1-14, 19-23, 26 and 27 is/are rejected.
- 7) ☒ Claim(s) 24 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 – 3, 14, 19 – 23, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,048,362 to Berg.

In reference to claims 1 -3, 14, 19 – 23, 26 and 27, Berg discloses applicant's claimed invention including an implantable elongated sleeve (Figure 1), the sleeve having opposed open ends and being formed from expandable material (Col. 2, lines 40 – 44), and at least a portion of the sleeve being visible under X ray fluoroscopy. Berg discloses a coating of X ray opaque material being on the outer surface of the sleeve (Col. 3, line 58 – Col. 4, line 6). The coating on the wire structure of the graph is considered by the examiner to meet the limitation of the X ray material comprising strips along the longitudinal dimension of the sleeve. The material forming the sleeve is capable of being severed. A recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus that differentiates it from a prior art reference disclosing the structural limitations of the claim. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1947); *In re Yanush*, 477 F.2d 958, 177 USPQ705 (CCPA 1973); *In re Finsterwalder*, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); *Ex parte Masham*, 2 USPQ2d 1647 (BbPatApp & Inter 1987).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 4 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,048,362 to Berg in view of U.S. Patent No. 6,361,557 to Gittings et al.

In reference to claims 4 - 13, Berg discloses the sleeve being visible under X ray fluoroscopy, but fails to disclose the X ray opaque material comprises strips embedded in the side wall, a plurality of markers being positioned adjacent to the openings, in a side-by-side relation, or being on the inner surface of the sleeve and being adhered to the sleeve. Gittings et al. discloses a sleeve having X ray opaque material comprises strips embedded in the side wall (Col. 8, line 61 – Col. 9, line 32). Gittings et al. discloses a plurality of markers (92) being positioned adjacent to the openings (Figure 4), in a side-by-side relation (92), being on the inner surface of the sleeve and being adhered to the sleeve (Col. 9, lines 8 – 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sleeve as disclosed by Berg to include the X ray opaque material in the arrangement as taught by Gittings et al. to improve the viewability of the sleeve to facilitate proper positioning.

Response to Arguments

Applicant's arguments filed 10/14/03 have been fully considered but they are not persuasive. Applicant has asserted that Berg fails to disclose applicant's claimed invention because of the limitations "to constrict and collapse the tissue of the body organ therein" and "for constricting

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and collapsing the body organ tissue” found in claims 1 and 14 respectively. However, these limitations are merely functional limitations and do not impose any structural limitation upon the claimed apparatus that differentiates it from a prior art reference disclosing the structural limitations of the claim. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1947); *In re Yanush*, 477 F.2d 958, 177 USPQ705 (CCPA 1973); *In re Finsterwalder*, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); *Ex parte Masham*, 2 USPQ2d 1647 (BbPatApp & Inter 1987).

Allowable Subject Matter

5. Claims 16- 18 and 28 – 32 are allowed. No prior art teaches or fairly suggests providing a sleeve being formed from an expandable material, the sleeve being dimensioned for constricting the body tissue to suppress flow of body fluid or air through the body tissue, and including an X ray opaque material visible under X ray fluoroscopy; drawing body tissue into the sleeve; and constricting and collapsing the body tissue with the sleeve.

6. Claims 24 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the

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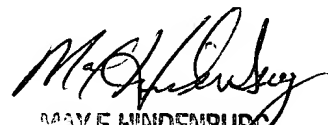
THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-872-9306 for regular communications and (703)-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.


JMLF
December 22, 2003


MAX F. HINDENBURG
SUPERVISOR
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